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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/982,992	PATTI ET AL.	
	Examiner	Art Unit	
	JaNa Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25,26 and 30-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25, 26 and 30-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 23, 2007 has been entered.

Amendment Entry

2. The amendment filed August 7, 2007 has been entered. Claim 30 has been amended. Claims 1-24 and 27-29 have been cancelled. Claims 25-26 and 30-32 are under consideration in this office action.

Withdrawal of Objections and Rejections

3. The following objections and rejections have been withdrawn in view of applicants' amendments and arguments:

a) The objection of the specification;

b) The rejection of claim 8 under 35 U.S.C. 112, second paragraph;

c) The deposit rejection of claim 30 under 35 U.S.C. 112, first paragraph;

d) The new matter rejection of claim 8 under 35 U.S.C. 112, first paragraph; and

e) The rejection of claims 1, 4, 6-12, 14, 18, and 23-24 under 35 U.S.C. 103(a) as being unpatentable over Hook et al., (US Patent 5,648,240) in view of Kohler and Milstein (Nature, 1975. Vol. 256:495-497).

Response to Arguments

4. Applicant's arguments with respect to claims 25-26 and 30-32 have been considered but are moot in view of the new ground(s) of rejection.

New Grounds of Objection

Specification

5. The amendment filed August 7, 2007 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The specification at page 33, line 14 adds a statement that the monoclonal antibody H07 was deposited on April 11, 2007 at ATCC. However the hybridoma cell line for the monoclonal antibody H07 deposited, not the actual antibody. See that Statement of Corroboration Under MPEP 2406.2, dated September 24, 2007. Thus, clarification is required to overcome the objection.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Objections

6. Claim 30 is objected to because of the following informalities: The claim states that monoclonal antibody H07 was deposited at the ATCC and bear Patent Deposit Designation PTA-8327; however the hybridoma cell line was deposited, not the antibody. Appropriate correction is required.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 30 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Neither the specification nor originally presented claims provides support for a monoclonal antibody which binds to an epitome that is recognized by monoclonal antibody H07, deposited at the ATCC and bearing Patent Deposit Designation PTA-8327.

Applicant did not point to support in the specification for a monoclonal antibody which binds to an epitome that is recognized by monoclonal antibody H07, wherein the

hybridoma was deposited at the ATCC and bearing Patent Deposit Designation PTA-8327. Moreover, applicant failed to specifically point to the identity or provide structural characteristics of the monoclonal antibody which binds to an epitome that is recognized by monoclonal antibody H07. Thus, there appears to be no teaching of a monoclonal antibody which binds to an epitome that is recognized by the deposited hybridoma which produces monoclonal antibody H07. Applicant has not pointed to pages of the instant specification or original claims for support of the amendment which is drawn to a monoclonal antibody binding to an epitome recognized by monoclonal antibody H07. Thus, it appears that the entire specification appears to fail to recite support for the newly recited monoclonal antibody that binds to an epitome recognized by monoclonal antibody H07. Therefore, it appears that there is no support in the specification. Therefore, applicants must specifically point to page and line number support for the identity of a monoclonal antibody which binds to an epitome that is recognized by monoclonal antibody H07, deposited at the ATCC and bearing Patent Deposit Designation PTA-8327 as recited by the amendment. Therefore, the claim incorporates new matter and is accordingly rejected.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 30-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP 2163.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.,* the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials. *Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . ."). *Regents of the University of California v. Eli Lilly & Co*., 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. The MPEP does state that for generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative, the Courts have indicated what do not constitute a representative number species to adequately describe a broad generic. *In Gostelli*, the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872 F.2d at 1012, 10 USPQ2d at 1618.

Claim 30 is drawn to a monoclonal antibody which binds to an epitome that is recognized by monoclonal antibody H07, which is produced by the hybridoma cell line

deposited at the ATCC, bearing Patent Deposit Designation PTA-8327. The specification describes monoclonal antibody H07. However, there is no description of a monoclonal antibody which binds to an epitome that is recognized by monoclonal antibody H07. Thus the written description in this case fails to set forth another specific monoclonal antibody having the ability to bind the same unknown epitome as H07. There is no teaching of multiple antibodies binding the same unknown epitome as H07. While the specification teach other MAP specific monoclonal antibodies such as H01, H04 and H10, there is no teaching that these antibodies bind to an epitome recognized by monoclonal antibody H07. There is no disclosure of the specific activity wherein a monoclonal antibody's binding is monitored to determine that is binds to an epitome recognized by H07. Therefore the written description is not commensurate in scope with the claims.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116). The possible structural variations are limitless to any class of polymer with any biomolecule. It must not be forgotten that the MPEP states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient as a characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence."

MPEP 2163. Here, though the claim recites the functional characteristic, i.e., binding to an epitome that is recognized by monoclonal antibody H07. However the claim lacks written description because there is no disclosure of a correlation between function and structure of a monoclonal antibody which binds to an epitome that is recognized by monoclonal antibody H07, which is produced by the hybridoma cell line deposited at the ATCC, bearing Patent Deposit Designation PTA-8327.

Moreover, the specification lack sufficient variety of species to reflect this variance in the genus since the specification does not provide any examples of monoclonal antibodies which binds to an epitome that is recognized by monoclonal antibody H07, which is produced by the hybridoma cell line deposited at the ATCC, bearing Patent Deposit Designation PTA-8327. The written description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. *See In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Claims 31-32 are drawn to an isolated antibody having a variable heavy sequence encoded by a nucleic acid sequence according to SEQ ID NO:3 or 5 or degenerates thereof. The written description in this case only sets forth the specific sequences, therefore the written description is not commensurate in scope with the

claims drawn to degenerates thereof. Neither the specification nor the claims teach how to define degenerates thereof. Neither the claims nor the specification teach how to obtain such degenerates. There is no guidance as to what the degenerates are; or what degenerates can or cannot be used within the antibody being claimed. The specification does not include structural examples of degenerates thereof. Thus, the resulting degenerate could result in a complexes not taught and enabled by the specification.

If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative, the Courts have indicated what do not constitute a representative number species to adequately describe a broad generic. In *Gostelli*, the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus as stated earlier, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that claims 31-32 are broad generic claims with respect all possible degenerates encompassed by the claims. The possible structural variations are limitless.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115). The skilled artisan cannot envision the detailed structure of the peptide fragments thereof, thus conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. An adequate description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. Furthermore, *In The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic

statement which defines a genus of by only their functional activity does not provide an adequate description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of molecules falling within the scope of the claimed genus.

In view of these considerations, a person skilled in the art would not have viewed the teachings of the specification sufficient to show that applicants were in possession of a monoclonal antibody which binds to an epitome that is recognized by monoclonal antibody H07, which is produced by the hybridoma cell line deposited at the ATCC, bearing Patent Deposit Designation PTA-8327 or isolated antibodies having a variable heavy sequence encoded by a nucleic acid sequence according to SEQ ID NO:3 or 5 or degenerates thereof as instantly claimed. Therefore the full breadth of the claims fail to meet the written description provision of 35 USC 112, first paragraph.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claim 30 is rejected under 35 U.S.C. 101 because a monoclonal antibody which binds to an epitome that is recognized by monoclonal antibody H07 is a product of nature. Antisera containing antibodies can be produced against the MAP10 protein. The claim does not require that the antibody be isolated. Insertion of the terms “isolated or purified” would obviate this rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claim 30 is drawn to a monoclonal antibody which binds to an epitome that is recognized by monoclonal antibody H07, deposited at the ATCC and bearing Patent Deposit Designation PTA-8327. However, it is still unclear how the instantly claimed antibody will recognize the same epitome recognized by the H07 antibody. It appears that the specification fails to point out what the specific epitome or binding regions recognized by monoclonal antibody H07. Therefore without such knowledge, it is unclear how one of ordinary skill in the art would be able to determine what the recognized epitome is pr whether the same epitome is being recognized by both the instantly claimed antibody and the monoclonal antibody H07, deposited at the ATCC and bearing Patent Deposit Designation PTA-8327. Thus, the metes and bounds of the term cannot be ascertained since there is no standard for determining the same epitome, the antibody recognition abilities or the structure of the instantly claimed antibody. Therefore, appropriate clarification is required to overcome the rejection.

b) Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention. Acronyms like ATCC must be spelled out when used for the first time in a chain of claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 26 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Wylie et al., (WO 96/39518).

Claim 26 is drawn to an isolated antibody having a variable heavy sequence according to SEQ ID NO:6. Claim 32 is drawn to an isolated antibody having a variable heavy sequence encoded by a nucleic acid sequence according to SEQ ID NO:5 or degenerates thereof.

Wylie et al., teach an amino acid sequence for a heavy chain fragment consisting of a heavy-chain variable region from a monoclonal antibody (page 4, para. 1). See also claim 12, page 59, and SEQ ID NO: 6. Wylie et al., also teach which is drawn to the heavy chain variable region nucleotide sequence (SEQ ID NO:5) and deduced amino acid sequence for a specific monoclonal antibody 8E7 (page 38, para. 4). The sequences of Wylie et al., have at least 80% sequence identity to the instantly recited SEQ ID NO:5-6.

It is noted that because of the language "having a variable heavy sequence according to SEQ ID NO:6" claim 26 is interpreted to comprise the full-length of SEQ ID NO:6 or any portion of SEQ ID NO:6. Furthermore, the language of claim 32 which recites "having a variable heavy sequence encoded by a nucleic acid sequence according to SEQ ID NO:5" is interpreted to comprise the full-length of SEQ ID NO:5 or any portion of SEQ ID NO:5.

Thus the claims are anticipated by any two amino acids, dinucleotides or any larger amino acid or oligonucleotide sequences. Therefore, Wylie et al., teach the instant claims.

Claim Rejections - 35 USC § 102

12. Claims 25 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Karasuyama et al. (EP 921189, published June 3, 1999).

Claim 25 is drawn to an isolated antibody having a variable heavy sequence according to SEQ ID NO:4. Claim 31 is drawn to an isolated antibody having a variable heavy sequence encoded by a nucleic acid sequence according to SEQ ID NO:3 or degenerates thereof.

Karasuyama et al., teach a molecule having an immunoglobulin structure comprising an immunoglobulin light chain structure [0020]. Karasuyama et al., teach a SEQ ID NO:4 which is a designated light chain of a mouse IgE and has 93.6% sequence identity to instantly claimed SEQ ID NO:4. Karasuyama et al., teach a SEQ ID

NO:3 which is described as DNA encoding the light chain of a mouse IgE and has 94.9% sequence identity to instantly claimed SEQ ID NO:3.

It is noted that because of the language "having a variable heavy sequence according to SEQ ID NO:4" as recited by claim 25 is interpreted to comprise the full-length of SEQ ID NO:4 or any portion of SEQ ID NO:4. Furthermore, the language of claim 31 which recites "having a variable heavy sequence encoded by a nucleic acid sequence according to SEQ ID NO:3" is interpreted to comprise the full-length of SEQ ID NO:3 or any portion of SEQ ID NO:3.

Thus the claims are anticipated by any two amino acids, dinucleotides or any larger amino acid or oligonucleotide sequences. Therefore, Karasuyama et al., teach the instant claims.

Conclusion

13. No claims allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JaNa Hines whose telephone number is (571)272-0859. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JaNa Hines/
Examiner, Art Unit 1645

/Mark Navarro/
Primary Examiner, Art Unit 1645